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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,048

01/26/2006

Philipp Hadwiger

A2038-7052US

3878

76634 7590 08/21/2008  
LOWRIE, LANDO & ANASTASI, LLP  
A2038  
ONE MAIN STREET, SUITE 1100  
CAMBRIDGE, MA 02142

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

NOTIFICATION DATE

DELIVERY MODE

08/21/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gengelso@ll-a.com  
docketing@ll-a.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/543,048	<b>Applicant(s)</b> HADWIGER ET AL.	
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 86,89,94-98,100-102 and 110-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86,89,94-98,100-102 and 110-119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/22/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/2008 has been entered.

### ***Status of Application/Amendment/Claims***

Applicant's response filed 07/22/2008 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 05/12/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. With entry of the amendment filed on 07/22/2008, claims 86, 89, 90, 94-98, 100-102, and 110-119 are pending in the application. Applicant has canceled claims 1-85, 87-88, 91-93, 99 and 103-109.

### ***Response to Applicant's Arguments***

#### ***Re: Claim Rejections - 35 USC § 103***

The rejection of claims 86, 89, 90, 94-98, 100-102, 110-119 under 35 U.S.C. 103(a) as being unpatentable over Rana, T. (US 2005/0020521) in view of Florence et

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al. (Journal of Controlled Release, 2000, Vol. 65: 253-259), Manoharan, M. (20030064492, "Manoharan I") and Cook et al. (U.S. Patent No. 6,803,198) and evidenced by Manoharan, M. (Applicant's IDS 02/13/2006, "Manoharan II") is maintained for the reasons of record in the Office action mailed 08/22/2007 and 05/12/2008.

Applicant's arguments filed 07/22/2008 have been fully considered but they are not persuasive. Applicant argues that the references, both alone and when read in combination would not render obvious the claimed invention. Specifically, Applicant argues Rana teaches away from the 5' modification as instantly claimed because Rana states the free 5' OH on the antisense strand of the siRNA duplex is required for RNA interference and therefore one of ordinary skill in the art would not have been motivated to modify the termini of siRNA.

Applicant's arguments are not convincing. Applicant is correct in that Rana et al. teach the 5' end of the antisense strand should contain a free OH group for efficient RNA interference, however Rana does not teach away from modifications of the 5' end of the sense strand. In fact, as pointed out in the previous Office actions at paragraph [0033], Rana teach preferred modifications of the ends of the strands include dendrimers. The instant independent claim 86 is not limited to modification of the 5' end of the antisense strand only, the claim is recited as the *5' end of the sense or antisense strand* can be modified with a lipophilic group and because Rana teach modifications of dsRNA at the 5' ends of a strand of the dsRNA and preferred modifications can comprise dendrimers, it would have been obvious to one of ordinary skill in the art to

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use the dendrimers taught by Florence et al. for attachment to a RNA strand, specifically at the 3' and 5' ends as taught by Rana, particularly given Florence et al. teach such dendrimers are efficient drug delivery vehicles for molecules.

Thus, the rejection of record is maintained.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
Art Unit 1635

/Sean R McGarry/

Primary Examiner, Art Unit 1635